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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/591,793

09/06/2006

Martin Edward Lee Pickford

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EXAMINER

LEADER, WILLIAM T

ART UNIT

PAPER NUMBER

1723

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DELIVERY MODE

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/591,793	Applicant(s) PICKFORD ET AL.	
	Examiner WILLIAM T. LEADER	Art Unit 1723	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 04 August 2010.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 13-15, 17, 19-21, 23-25, 27-29, 31 and 33 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 13-15, 17, 19-21, 23-25, 27-29, 31 and 33 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>5/31/2010</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. Receipt of the papers filed on August 4, 2010, is acknowledged. Claims 22 and 32 have been canceled. Claims 13-15, 17, 19-21, 23-25, 27-29, 31 and 33 are pending.

2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim Rejections - 35 USC § 103

3. Claims 13-15, 17, 19-21, 23-25, 27, 28, 31 and 33 are rejected under 35 U.S.C. 103(a) as being unpatentable over Pickford et al (WO 03/089023) in view of O'Brien et al (US 7,488,343) for the reasons of record.

4. Claim 29 is rejected under 35 U.S.C. 103(a) as being unpatentable over Pickford et al (WO 03/089023) in view of O'Brien et al (US 7,488,343) as applied to claims 13-15, 17, 19-21, 23-25, 27, 28, 31 and 33 above, and further in view of Rosenberg et al (US 5,185,075) for the reasons of record.

5. Claims 13-15, 17, 19-21, 23-25, 27-29, 31 and 33 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cooper et al (US 5,211,832), newly cited, in view of Pickford et al (WO 03/089023).

6. Applicant has amended independent claims 13 and 24 to recite additional limitations related to the characteristics of the layer produced by anodizing. The Cooper et al patent (hereinafter Cooper) is directed to a process for anodizing titanium and titanium alloys. See the abstract. In examples 6, 7 and 8 (column 6) a titanium workpiece was anodized in a phosphoric acid solution at an applied voltage of 75V or 100V for a period of time greater than 30 minutes. These are the same anodizing conditions disclosed and claimed by applicant. Because the process steps are the same, the characteristics of the anodized layer of Cooper would have been expected to be the same as those of applicant's layer as recited in claims 13, 21, 23, 24 and 33. Cooper et al discloses that the anodized layer formed on the titanium workpieces is excellent as a protective coating for surgical implants (column 6, lines 44-48). The process recited by applicant differs from the process of Cooper by reciting adding ions of a biocidal metal by ion exchange. Pickford is interpreted as above and discloses a method for making a titanium implant by anodizing. Pickford recognizes that there is a risk of introducing infection when implanting a metal implant, and notes that it has been suggested to incorporate a biocidal material such as silver that can control infection without causing toxic effects to the patient (page 1, lines 14-19). Pickford discloses incorporating silver into a layer formed by anodizing a titanium implant by ion exchange. See page 5, lines 14-17. It would have been obvious at the time the invention was made to have incorporated silver into the anodized layer of the titanium workpiece of Cooper as taught by Pickford because the risk of infection would have been reduced when the workpiece was used as an implant.

7. With respect to claims 14 and 15, as noted above, Cooper discloses the use of titanium and titanium alloys. See the abstract.
8. With respect to claim 17, Pickford discloses that the biocidal metal ions are absorbed into the oxide or phosphate matrix formed by anodizing. See page 3, lines 33-36 and page 5, lines 14-17.
9. With respect to claims 19 and 25, Pickford discloses that silver, gold, platinum, and palladium are suitable biocidal materials (page 2, lines 20-28).
10. With respect to claim 20, anodizing at 100 V as disclosed by Cooper would have been expected to produce a thickness of 0.14 micrometers in the same manner as it does in applicant's process. See page 5, lines 15-17 of the specification.
11. With respect to claims 27 and 28, as noted above, both Cooper and Pickford disclose anodizing in an electrolyte comprising phosphoric acid. Pickford shows that the use of a phosphoric acid solution with concentration falling within the range recited by applicant is known
12. With respect to claim 29, Cooper discloses that the presence of halide in the anodizing solution is undesirable since chloride ions tends to create tunnels and pits in the anodized film (column 3, lines 29-31). . It would have been obvious to have controlled the amount of chloride to a small value because Rosenberg teaches that an excessive amount may be harmful to the anodizing process.

13. With respect to claim 31, Pickford discloses that other elements including copper, tin antimony, lead, bismuth and zinc may be used as ions combined into the matrix of oxide of phosphate. See page 2, lines 30-33.

Response to Arguments

14. Applicant's arguments filed August 3, 2010, have been fully considered but they are not persuasive. Applicant has amended independent claim 24, which is directed to a method, to recite additional characteristics of the product that is produced by the method. These additional limitations are not considered to distinguish the method recited in claim 24 from the prior art of record. Applicant has added similar limitations to independent claim 13.

15. At page 6 of the Remarks, applicant argues that O'Brien does not provide the recitations missing from Pickford and recited in independent claims 13 and 24. This argument is not convincing. As set forth in the previous office action, Pickford is directed to the manufacture of metal implants. The implant may be made of titanium alloy which is very strong and relatively light (page 1, lines 11-12). The implant comprises a metal substrate and a surface layer that is integral with the metal substrate and which incorporates a biocidal metal (page 1, lines 25-29). The integral surface layer may be generated by growing the layer from the metal itself, for example by an anodizing process (page 1, line 34-36). Silver is the preferred biocidal metal (page 2, lines 25-28). In an example at page 5, lines 1-23, an implant made of titanium alloy was anodized in a 12 wt% solution of phosphoric acid for 2 hours at a maximum voltage of 10V so as to form a surface coating of titanium phosphate. Subsequently, the implant was immersed in an

aqueous solution of silver nitrate. This results in the formation of some silver phosphate in the titanium phosphate coating. The process recited in independent claim 24 differs from the process of Pickford by reciting anodizing at a voltage above 50V. Thus, the only process limitation missing from Pickford is the use of a voltage of 50V rather than 10V. Contrary to applicant's argument, this limitation is taught by O'Brien which discloses anodizing titanium in a phosphoric acid solution at voltages ranging from 5 to 100 volts. As shown by O'Brien, process parameters such as voltage may be varied to obtain an oxide layer with the desired characteristics. Choice of a higher voltage within the range disclosed by O'Brien would have been expected to produce variations in the oxide layer such as larger openings, thereby allowing the incorporation of a greater amount of material into the openings, and a thicker oxide layer. Variation of voltage in the process of Pickford by choosing a value from within the voltage range disclosed by O'Brien to vary oxide parameters would have been obvious. See MPEP 2144.05. Applicant has not presented evidence demonstrating unexpected results for the claimed process of a scope commensurate with the claim limitations. See MPEP 716.02.

16. At page 7 of the Remarks, applicant contends that anodizing at a voltage above 50 volts in the method of Pickford would be contrary to one of the purposes of Pickford which is to form a surface that has significant ion exchange properties so that it can absorb silver ions. Applicant argues that anodizing at a voltage above 50 volts with an electrolyte such as phosphoric acid would provide Pickford a surface with very poor ion exchange properties because the entire surface would be covered by a hard oxide layer. This argument is not persuasive. Since the only difference between applicant's claimed process and the process of Pickford is the use of an

anodizing voltage above 50V, employing a voltage above 50 volts in the process of Pickford would be the equivalent of applicant's process. Applicant's process is described at page 4, line 34 to page 5, line 17 and includes anodizing a titanium alloy implant in a 12 wt% solution of phosphoric acid for 2 hours at a maximum voltage of 100 volts to form a surface coating of titanium oxide and phosphate. As described at page 5, lines 19-22, silver phosphate is formed as a result of ion exchange. Thus, the surface produced by applicant is receptive to ion exchange. Applicant has not advanced any cogent explanation as to why applicant would obtain an implant with one set of properties when anodizing as described at pages 4 and 5 of the specification, while performing Pickford process steps using a voltage above 50 volts would result in an implant with different set of properties.

17. Applicant's arguments with respect to the dependent claims at pages 7 and 8 of the Remarks have been considered but are not deemed to be persuasive for the reasons given above.

18. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Minevski et al (US 2004/0121290) is directed to biocompatible implants. The implants may be made of titanium. See the abstract. The implant may be treated by anodizing in an aqueous phosphoric acid solution. The concentration of the solution may be between 0.01N and about 5.0N. The temperature of the solution is between 15 and 65°C. The electric potential may be between about 10 and 150 volts. Duration of treatment may be between about 15 seconds and about 2 hours. See paragraph [0031]. The anodizing conditions disclosed and claimed by applicant fall within the ranges set forth by Minevski.

Conclusion

19. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to WILLIAM T. LEADER whose telephone number is (571) 272-1245. The examiner can normally be reached on Mondays-Thursdays and alternate Fridays, 7:30-4:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Alexa D. Neckel can be reached on 571-272-1446. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/William Leader/
October 5, 2010

/Alexa D. Neckel/
Supervisory Patent Examiner, Art Unit 1723